



American Academy of Otolaryngology – Head and Neck Surgery, Inc.

DEDICATED TO CARE OF THE EARS, NOSE, THROAT, AND RELATED STRUCTURES OF THE HEAD AND NECK

One Prince Street

Alexandria, VA 22314-3357 USA

(703) 836-4444 FAX: (703) 683-5100 TTY: (703) 519-1585 www.entnet.org

2000-2001 ACADEMY BOARD OF DIRECTORS

Officers

Jack L. Gluckman, MD
President
Cincinnati, OH

K.J. Lee, MD
President-Elect
New Haven, CT

Richard L. Mabry, MD
Vice-President
Dallas, TX

Fred D. Owens, MD, MBA
Secretary-Treasurer
Dallas, TX

G. Richard Holt, MD, MPH
Executive Vice President
Alexandria, VA

Immediate Past President
John G. Campbell, MD
Tulsa, OK

At-Large Directors
M. Jennifer Derebery, MD
Los Angeles, CA

James A. Hadley, MD
Rochester, NY

David W. Kennedy, MD
Philadelphia, PA

William W. Shockley, MD
Chapel Hill, NC

James Y. Suen, MD
Little Rock, AR

J. Regan Thomas, MD
Chicago, IL

Board of Governors

Michael Setzen, MD
Chair
Manhasset, NY

Joseph E. Leonard, MD
Chair-Elect
Norman, OK

C. Ron Cannon, MD
Immediate Past Chair
Jackson, MS

Coordinators

Ronald B. Kupper-Smith, MD
Internet and Information Technology
Seattle, WA

Willard B. Moran, Jr., MD
Socioeconomic Affairs
Edmond, OK

Ira D. Papel, MD
Governmental Relations
Owings Mills, MD

Gary T. Turner, MD
Practice Affairs
Birmingham, AL

April 20, 2001

Sandra L. Titus

Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5630 Fishers Lane (Room 1093)
Rockville, MD 20857

Dear Ms. Titus:

The American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) is pleased to provide the Nonprescription Drugs Advisory Committee and the Pulmonary-Allergy Drugs Advisory Committee with comment on citizen petition 98P-0610/CP1, submitted by Blue Cross of California. The petition requested that the agency convert the antihistamines, Allegra (fexofenadine hydrochloride), Claritin (loratadine), and Zyrtec (cetirizine hydrochloride) to over-the-counter (OTC) status. We understand that these committees will be meeting jointly on May 11, 2001 to consider this issue.

The AAO-HNS is the national medical specialty association of physicians dedicated to the care of the patients with diseases and disorders and the ears, nose, throat, and related structures of the head and neck. As otolaryngologists, we are commonly referred to as ENT physician specialists. We have a membership of over 12,000 otolaryngologists worldwide and a special interest in the issue.

The above named pharmaceuticals, otherwise known as second generation antihistamines, are currently prescribed by physicians for their patients primarily for the treatment of allergic rhinitis or allergic rhinosinusitis. We believe that it is critical for patients with severe allergy problems to see a physician, preferably an otolaryngologist, to have the cause and extent of their symptoms medically diagnosed, managed and treated. Patients are not necessarily in a position to diagnose themselves or know what medication to use. Nasal polyps or a tumor causing nasal obstruction, and not allergies, may be the problem.

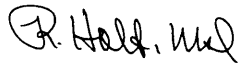
There is a great public health risk in inappropriate and/or over utilization of these potent second generation drugs owing to inaccurate self-diagnosis and potential overmedication. In addition, we believe that pharmacists provide important patient education on adverse interactions of drugs. Patients will be



less likely to avail themselves of this expert advice if they are led to believe that the OTC classification implies the pharmacist's expertise is unnecessary and no adverse interaction is possible. Consequently, we believe it is in the patients' best interest for FDA to refrain from converting these second generation antihistamines to OTC status.

Thank you for the opportunity to submit our views. Should the committees or the FDA require additional information, please contact Beverly Nissenbaum in our health policy and government affairs department on (703) 519-1537.

Sincerely,

A handwritten signature in black ink, appearing to read "G. Holt, MD". The signature is cursive and somewhat stylized.

G. Richard Holt, MD, MPH
Executive Vice President